

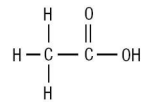
## **ACETIC ACID - acetic acid solution**

Morton Grove Pharmaceuticals, Inc.

### **DESCRIPTION**

Acetic Acid Otic Solution, USP is a nonaqueous solution of glacial acetic acid, USP (2%), in a propylene glycol vehicle containing benzethonium chloride, USP (0.02%); propylene glycol diacetate, NF (3%) and sodium acetate, USP (0.015%). **It may also contain citric acid, USP.**

The molecular formula for acetic acid is CH<sub>3</sub>COOH, with a molecular weight of 60.05. The structural formula is:



Acetic Acid Otic Solution is available as a nonaqueous otic solution buffered at pH 3 for use in the external ear canal.

### **CLINICAL PHARMACOLOGY**

Acetic acid is anti-bacterial and anti-fungal; propylene glycol is hydrophilic and provides a low surface tension; benzethonium chloride is a surface active agent that promotes contact of the solution with tissues.

### **INDICATIONS AND USAGE**

For the treatment of superficial infections of the external auditory canal caused by organisms susceptible to the action of the antimicrobial.

### **CONTRAINDICATIONS**

Hypersensitivity to Acetic Acid Otic Solution or any of the ingredients. Perforated tympanic membrane is considered a contraindication to the use of any medication in the external ear canal.

### **WARNINGS**

Discontinue promptly if sensitization or irritation occurs.

### **PRECAUTIONS**

Transient stinging or burning may be noted occasionally when the solution is first instilled into the acutely inflamed ear.

### **Pediatric Use**

Safety and Effectiveness in pediatric patients below the age of 3 years have not been established.

### **ADVERSE REACTIONS**

Stinging or burning may be noted occasionally; local irritation has occurred very rarely.

### **DOSAGE AND ADMINISTRATION**

Carefully remove all cerumen and debris to allow Acetic Acid Otic Solution to contact infected surfaces directly. To promote continuous contact, insert a wick of cotton saturated with the solution into the ear canal; the wick may also be saturated after insertion. Instruct the patient to keep the wick in for at least 24 hours and to keep it moist by adding 3 to 5 drops of the solution every 4 to 6 hours. The wick may be removed after 24 hours but the patient should continue to instill 5 drops of Acetic Acid Otic Solution 3 or 4 times daily thereafter, for as long as indicated. In pediatric patients, 3 to 4 drops may be sufficient due to the smaller capacity of the ear canal.

### **HOW SUPPLIED**

Acetic Acid Otic Solution USP, 2% is supplied in 15 mL measured drop, safety-tip plastic bottles.

### **RECOMMENDED STORAGE**

**Store at controlled room temperature, 15 °–30 °C (59 °–86 °F).**

**KEEP CONTAINER TIGHTLY CLOSED**

### **Rx Only**

Product No.: 8741

### **Manufactured By:**

**Morton Grove Pharmaceuticals, Inc.**

**Morton Grove, IL 60053**

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